

REMARKS

The invention relates to an internal substance delivery device particularly useful for delivery of drugs into body cavities. The internal substance delivery device includes a support frame having at least two resilient arms which retain the internal substance delivery device against a mucosal membrane of the body cavity, wherein each arm is capable of releasing a separate pod capable of releasing a drug contained within a matrix of the pod, wherein the resilient arms are biased outward from a central section of the support frame and wherein at least one of the pods is flexibly attached to a corresponding arm by a ball and socket mechanism allowing full movement of the pod with respect to the support frame and enabling the internal substance delivery device to contact the mucosal membrane of the body cavity.

Upon entry of the present amendment, Claims 1, 3-5, 8-9, 11-14 and 17-21 will be pending in this application. Claims 1 and 3 are currently amended. Claim 21 is new. Claims 2, 6-7, 10 and 15-16 were previously cancelled without prejudice. No new matter is added and support for the amendments can be found throughout the instant application.

Interview Summary

Applicants and applicants' representative wish to thank the Examiner for participating in a telephonic interview conducted April 15, 2008, to discuss the remaining rejections. Applicants especially thank the Examiner for helpful discussions with respect to the proposed claim amendments.

The 35 U.S.C. §102(b) rejection of Claims 1, 4-5, 8, 12-13 and 17 as being anticipated *Hiller et al.*, (US 4,369,783); rejection of Claims 11 and 20 as being obvious over *Hiller et al.*, (already of record) and rejection of Claims 3, 9, 14, 18 and 19 as being obvious over *Hiller et al.*, (already of record) in view of *Anderson et al.*, (US 5,816,248) were discussed. A final agreement was not reached because applicants had not submitted proposed claim amendments on the record. Applicants respectfully submit the claims are

amended herein to incorporate the claim amendments discussed during the telephonic interview. Accordingly, Applicants respectfully request withdrawal of the remaining rejections and issuance of a Notice of Allowance.

Allowable Subject Matter

In the Non-Final Office Action mailed November 11, 2006, the Examiner objected to Claim 7 for being dependent upon a rejected base claim, but stated the claim would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claim. Applicants respectfully submit that Claim 7 was cancelled in the Amendment and Response to Office Action filed October 16, 2007, and that the subject matter of Claim 7 was incorporated into Claim 1. Accordingly, applicants respectfully submit Claim 1 is in the form for allowance and kindly request issuance of a Notice of Allowance.

Rejections based on 35 U.S.C. §102(b)

In the Non-Final Office Action mailed December 10, 2007, Claims 1, 4-5, 8, 12-13 and 17 were rejected under 35 U.S.C. §102(b) as being anticipated by Hiller *et al.*, (US 4,369,783). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite that the internal substance delivery device is retained **against a mucosal membrane** of the body cavity. Additionally, Claim 1 is also amended herein to recite that the at least two resilient arms are **biased outward**, and that at least one pod is flexibly attached to a corresponding ball and socket mechanism **allowing full movement of the pod with respect to the support frame and enabling the internal substance delivery device to contact the mucosal membrane of the body cavity**. Applicants respectfully submit Hiller *et al.*, fail to teach or suggest an internal substance delivery device wherein the delivery device includes at least

two resilient arms that are **biased outward** from the support frame. Furthermore, applicants respectfully submit Hiller *et al.*, fail to teach or suggest an internal substance delivery device wherein the delivery device includes at least two resilient arms that are **biased outward** from the support frame and wherein at least one **pod is allowed full movement with respect to the support frame**, as recited in amended Claim 1. Applicants respectfully submit support for the above amendment can be found on at least page 8, lines 15-19; page 9, lines 1-2; page 11, lines 1-5 of the substitute sheets.

Applicants submit Hiller *et al.*, is directed to a nose-clip in cattle wherein the support frame is **biased inward** so that the nose-clip can be attached to a nasal septum. For example, applicants direct the Examiner to column 1, lines 39-45 of Hiller *et al.*, that discloses a nose-clip “which consists of a resilient, U-shaped bow whose ends are **inclined towards each other** and turned to face each other....” (*emphasis added*). Applicants respectfully submit that Hiller *et al.*, fail to teach or suggest biased outward resilient arms as claimed herein. The amended claims recite a support frame with biased outward resilient arms and that at least one pod is flexibly attached to a corresponding ball and socket mechanism **allowing full movement of the pod with respect to the support frame and enabling the internal substance delivery device to contact the mucosal membrane of the body cavity**, thus allowing the internal substance delivery device to be retained in the body cavity.

Applicants submit that Hiller *et al.*, fail to teach or suggest an internal substance delivery device as structurally defined herein and kindly request withdrawal of the rejection.

Rejections based on 35 U.S.C. §103(a)

In the Non-Final Office Action mailed December 10, 2007, Claim 11 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite structural features of the internal substance delivery device that are not taught or suggested by Hiller *et al.* Claim 11 depends indirectly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite **biased outward** resilient arms, and that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the **pod is in contact with the mucosal membrane of the body cavity**. Applicants respectfully submit that based on the dependency of Claim 11 on amended Claim 1, that Claim 11 is now in a form for allowance. Accordingly, applicants kindly request withdrawal of the rejection of Claim 11 under 35 U.S.C. §103(a).

In the Non-Final Office Action mailed December 10, 2007, Claim 20 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite structural features of the internal substance delivery device that are not taught or suggested by Hiller *et al.* Claim 20 depends directly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite **biased outward** resilient arms, and that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the **pod is in contact with the mucosal membrane of the body cavity**. Applicants respectfully submit that based on the dependency of Claim 20 on amended Claim 1, that Claim 20 is now in a form for allowance. Accordingly, applicants kindly request withdrawal of the rejection of Claim 20 under 35 U.S.C. §103(a).

In the Non-Final Office Action mailed December 10, 2007, Claim 3 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record) in view of Anderson *et al.*, (US 5,816,248). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite structural features of an internal substance delivery device that are not taught or suggested by Hiller *et al.*, or Anderson *et al.* Applicants respectfully submit Claim 3 depends directly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite **biased outward** resilient arms and that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the pod is in contact with the mucosal membrane of the body cavity. Applicants respectfully submit that Hiller *et al.*, alone, or combination with Anderson *et al.*, fail to teach or suggest the claimed invention for at least the following reasons.

As discussed under 35 U.S.C. rejection under §102(b), Hiller *et al.*, fails to teach **biased outward** resilient arms. Applicants respectfully submit Hiller *et al.*, discloses **biased inward** arms that “are **inclined towards each other**” (see column 1, lines 39-45). The deficiencies of Hiller *et al.*, are not satisfied by Anderson *et al.*, for at least the following reasons.

Anderson *et al.*, fails to teach or suggest an internal substance delivery device wherein the at least one pod is **flexibly attached** to a corresponding arm by a **ball and socket mechanism**. Additionally, Anderson *et al.*, fails to teach or suggest that the at least one pod attached to the corresponding arm by a ball and socket mechanism **allows full movement of the pod with respect to the support frame**, such that the pod is in contact with the mucosal membrane of the body cavity.

Applicants respectfully submit there is no suggestion or motivation for one of ordinary skill in the art to modify the device's of Anderson *et al.*, and Hiller *et al.*, to incorporate a flexibly attached ball and socket mechanism. Applicants also submit there is no motivation or suggestion in the art to devise an internal drug delivery device wherein at least one pod is attached to a corresponding arm such that full movement of the pod with respect to the support frame can occur, i.e., the pod is in contact with the mucosal membrane of the body cavity. In contrast, the claimed device includes resilient arms that are biased outward

and that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the pod is in contact with the mucosal membrane of the body cavity. Based on the dependency of Claim 3 on amended Claim 1, applicants respectfully submit that Claim 3 is now in a form for allowance. Accordingly, applicants kindly request withdrawal of the rejection of Claim 3 under 35 U.S.C. §103(a).

In the Non-Final Office Action mailed December 10, 2007, Claim 9 was rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record) in view of Anderson *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite structural features of an internal substance delivery device that are not taught or suggested by Hiller *et al.*, or Anderson *et al.* Applicants respectfully submit Claim 9 depends directly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite **biased outward** resilient arms and that at least one pod attached to the corresponding arm allows **full movement of the pod with respect to the support frame**, such that the pod is in contact with the mucosal membrane of the body cavity. Applicants respectfully submit that Hiller *et al.*, alone, or combination with Anderson *et al.*, fail to teach or suggest the claimed invention. Specifically, applicants respectfully submit Hiller *et al.*, discloses **biased inward** arms that “are **inclined towards each other**” (see column 1, lines 39-45). Anderson *et al.*, fails to teach or suggest an internal substance delivery device wherein the at least one pod is **flexibly attached** to a corresponding arm by a **ball and socket mechanism**. Additionally, Anderson *et al.*, and Hiller *et al.*, fail to teach or suggest that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the pod is in contact with the mucosal membrane of the body cavity. Based on the dependency of Claim 9 on amended Claim 1, applicants respectfully submit that Claim 9 is

now in a form for allowance. Accordingly, applicants kindly request withdrawal of the rejection of Claim 9 under 35 U.S.C. §103(a).

In the Non-Final Office Action mailed December 10, 2007, Claims 14, 18 and 19 were rejected under 35 U.S.C. §103(a) as being obvious over Hiller *et al.*, (already of record) in view of Anderson *et al.*, (already of record). Applicants respectfully submit that amendments to the claims overcome the rejection.

Applicants respectfully submit that Claim 1 is amended herein to recite structural features of an internal substance delivery device that are not taught or suggested by Hiller *et al.*, or Anderson *et al.* Applicants respectfully submit Claims 14, 18 and 19 depend indirectly on amended Claim 1. As discussed above, Applicants have amended claim 1 to recite **biased outward** resilient arms and that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the pod is in contact with the mucosal membrane of the body cavity. Applicants respectfully submit that Hiller *et al.*, alone, or combination with Anderson *et al.*, fail to teach or suggest the claimed invention.

As discussed above, Hiller *et al.*, fails to teach **biased outward** resilient arms. Furthermore, Anderson *et al.*, fails to teach or suggest an internal substance delivery device wherein the at least one pod is **flexibly attached** to a corresponding arm by a **ball and socket mechanism**. Additionally, Anderson *et al.*, fails to teach or suggest that at least one pod attached to the corresponding arm allows full movement of the pod with respect to the support frame, such that the pod is in contact with the mucosal membrane of the body cavity.

Applicants respectfully submit there is no suggestion or motivation for one of ordinary skill in the art to modify the device's of Anderson *et al.*, and Hiller *et al.*, to derive the claimed invention. Based on the dependency of Claims 14, 18 and 19 on amended Claim 1, applicants respectfully submit that Claims 14, 18 and 19 are in the form for allowance. Accordingly, applicants kindly request withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In light of the amendments and the above remarks, Applicants are of the opinion that the Non-Final Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to Dr. Zara Doddridge at (404)-815-6473 is respectfully solicited.

Respectfully submitted,

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